Substitute Form PTO-1449 (Modified)	PTO-1449 U.S. Department of Commerce Patent and Trademark Office		Application No.	
Information Disclosure Statement by Applicant		Applicant Bäckström et al.		
(Use several sho	eets if necessary)	Filing Date	Group Art Unit	
(37 CFR §1.98(b))				

	U.S. Patent Documents							
Examiner (Initial	Desig.	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appro priate	
X	AA	2,992,645	07/18/61	Fowler			priato	
	AB	3,014,844	12/26/2001	Thiel				
	AC	3,671,625	06/1972	Altounyan				
	AD	3,911,138	10/07/1975	Clark	424	352		
	AE .	4,232,002	11/1980	Nogrady				
	AF	4,462,983	07/1984	Azria			-	
	AG	4,524,769	06/25/1985	Wetterlin	128	203.15		
	AH	4,534,345	08/13/1985	Wetterlin	128	203.15		
	AI	4,537,772	08/1985	Alexander				
	AJ	4,548,922	10/22/1985	Carey et al.	514	4		
AL	AK	4,613,500	09/23/1986	Suzuki et al.	424	85.4		
	AL	4,668,218	05/26/2987	Virtanen	604	58		
	AM	4,690,952	09/01/1987	Kagatani et al.	514	-11		
	AN	4,731,360	03/1988	Alexander				
	AO	4,746,508	05/24/1988	Carey et al.	424	-88		
	AP	4,788,221	11/29/1988	Kagatani et al.	514	12		
	AQ	4,847,298	04/11/1989	Alexander				
	AR	4,895,719	01/23/1990	Radhakrishnan				
	AS	4,900,730	02/13/1990	Miyauchi	514	-12		
	AT	4,907,583	03/13/1990	Wetterlin et al.	128	203.1 5		
	AU	4,914,084	04/03/1990	Ecanow	514	006		
	AV	4,920,061	04/24/1990	Poynton	436	-526		
	AW	4,926,852	05/22/90	Zoltan et al.	128	200.23		
CYA	AX	4,959,358	09/28/1998	Carey et al.	514	171		
XX	AY	4,963,367	10/16/1990	Ecanow	T			
		1 1.0						

Examiner Signature	Date Considered
A burn V / / / War	7 1-06
a swid Ly/Man	1-1-00
EXAMINER: Initials citation considered. Draw line through citation if no	t in conformance and not considered. Include conv of this form with
next communication to applicant	The second secon

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-004003	Application No.	
Information Disclosure Statement by Applicant		Applicant Bäckström et al.		
(Use several s	heets if necessary)	Filing Date	Group Art Unit	
(37 CFR §1.98(b))				

			U.S. Patent	Documents			
Examiner	Desig.	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appro priate
\	AZ	4,994,439	02/19/1991	Longnecker			•
1	AAA	5,006,343	04/09/1991	Benson			
	ABB	5,011,678	04/30/1991	Wang			
	ACC	5,118,494	06/02/1992	Schultz			
	ADD	5,122,127	06/16/1992	Stanley			
	AEE	5,122,376	06/16/1992	Aliverti			
	AFF	5,179,079	01/12/1993	Hansen et al.	514	4	
	AGG	5,192,548	03/09/1993	Velasquez et al.		_	
	АНН	5,200,393	04/06/1993	Weiner			
$\bigcap_{i=1}^{N}$	AII	5,202,129	04/13/1993	Samejima et al.	424	489	
XX.	AJJ	5,254,330	10/19/1993	Ganderton et al.			
	AKK	5,260,306	11/09/1993	Boardman et al.			
	ALL	5,284,656	02/08/1994	Platz et al.	424	435	
	AMM	5,288,498	02/22/1994	Stanley et al.			
	ANN	5,320,094	06/14/1994	Laube et al.	128	203.12	
	AOO	5,341,800	08/30/1994	Clark et al.	128	203.15	
	APP	5,348,730	09/20/1994	Greenleaf			
	AQQ	5,349,947	09/27/1994	Newhouse et al.	128	203.21	
	ARR	5,352,461	10/04/1994	Feldstein et al.	424	493	
	ASS	5,354,562	10/11/1994	Platz et al.	424	489	
	ATT	5,364,838	11/15/1994	Rubsamen	514	3	
	AUU	5,376,359	12/1994	Johnson			
, ,	AVV	5,376,386	12/27/1994	Ganderton et al.			
	AWW	5,384,133	01/24/1995	Boyes et al.			
SA	AXX	5,384,133	01/24/1995	Bäckström et al.			

Examiner Signature / / (/ / / / / / / / / / / / / / / /	Date Considered C
Volvix hyllen) ~ (~ 0 6
	\sim 1 \sim 0
EXAMINER: Initials citation considered. Draw line through citation if no	It in conformance and not considered. Include copy of this form with
next communication to applicant	

10-792201

Sheet <u>3</u> of <u>10</u>

Substitute Form PTO-1449 (Modified)			Application No.	
i		Applicant Bäckström et al.		
(Use several sh	neets if necessary)	Filing Date	Group Art Unit	
(37 CFR §1.98(b))	Information Disclosure Statement by Applicant (Use several sheets if necessary)			

U.S. Patent Documents								
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appro priate	
ZZ	AYY	5,419,315	05/30/1995	Rubsamen	128	200.14		
	AZZ	5,437,271	08/01/1995	Hodson et al.				
	BA	5,437,271	08/01/1995	Bäckström et al.				
	ВВ	5,451,569	09/19/1995	Wong et al.	514	3		
	BC	5,458,135	10/17/1995	Patton et al.	128	200.14		
	BD	5,474,759	12/1995	Fassberg et al.				
	BE	5,482,032	01/09/1996	Smith et al.				
	BF	5,482,706	01/09/1996	Igari et al.				
1)	BG	5,506,203 C1	04/1996	Bäckström et al.				
	ВН	5,514,670	06/07/1996	Friedman				
	BI	5,518,998 C1	02/2001	Bäckström et al.				
	ВЈ	5,607,915	03/04/1997	Patton	514	12		
	BK	5,658,878	08/1997	Bäckström et al.				
	BL	5,661,130	08/26/1997	Meezan et al.	514	25		
	ВМ	5,707,644	01/13/1998	Jillem				
	BN	5,730,969	03/24/1998	Hora et al.	424	85.1		
	ВО	5,747,445	05/1988	Bäckström et al.				
	BP	5,814,607	09/29/1998	Patton	514	12		
	BQ	5,830,853	11/1998	Bäckström et al.				
	BR	5,858,968	01/1999	Weiner et al.				
	BS	5,952,008	09/1999	Bäckström et al.				
	ВТ	5,997,848	12/07/1999	Patton et al.	424	46		
1	BU	6,004,574	12/1999	Bäckström et al.				
	BV	6,051,256	04/18/2000	Platz et al.	424	489		
2/1	BW	6,165,976	12/2000	Bäckström et al.				

	\bigcirc \triangle	$-\Omega$		
Examiner Signature	1) 1	-DID	Date Considered	A C
<i>l</i>	/be with	Lu/R Son	1 2-1.	- 0 (p
EXAMINER: Initials ci	tation considered	Draw line through citation if	not in conformance and not consider	red. Include copy of this form with
payt communication to		o.a aoag o.aaao		

Substitute Disclosure Form (PTO-1449)

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-004003	Application No.		
by A	Information Disclosure Statement by Applicant (Use several sheets if necessary)	Applicant Bäckström et al.			
(Use several si	heets if necessary)	Filing Date	Group Art Unit		
(37 CFR §1.98(b))					

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appro priate
ZZ N	BX	6,306,440	10/2001	Bäckström et al.			
0,26	BY	6,436,902 B1	8/2002	Bäckström et al.			
X De	BZ	6,524,557	02/2003	Bäckström et al.			
	BAA	6,534,557					
XX.	BBB	20030064928 A1		Bäckström et al.			
\sim	BCC-	08/60 1,005					
X	BDD-	08/736,267					
\angle	BEE_	-08/906 ,825					
	BFF	08/960,0 93					
X	BGG	09/072,7 17					
, X	вин	09/158,554					
X	BII	-09/383,590 -					
X	BH	-09/665,58 5					
λ	BKK	09/731,429					
X	BLL	09/783,18 9					
X	BMM_	10/224,522					,
X	BNN	10/401,157					
X	BOO_	1 0/401,1 81					

	Foreign Patent Documents or Published Foreign Patent Applications								
Examiner	Desig.	Document	Publication	Country or				slation	
Initia	ID	Number	Date	Patent Office	Class	Subclass	Yes	No	
	BPP	0 023 359	07/29/1980	Europe					
	BQQ	0 055 041	12/03/1981	Europe					
	BRR	0 122 036	10/17/1984	Europe					
	BSS	0 128 831	12/19/1984	Europe					
\bigvee	ВТТ	9 133 252 AZ	02/1985	Europe					
Examiner Sign	nature			Date Considered					

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Disclosure Form (PTO-1449)

	Department of Commerce ent and Trademark Office	Attorney's Docket No. 06275-004003	Application No.
Information Disclosure S by Applicant	Statement	Applicant Bäckström et al.	
(Use several sheets if necessary)		Filing Date	Group Art Unit
(37 CFR §1.98(b))			

	Foreign Patent Documents or Published Foreign Patent Applications							
Examiner	Desig.	Document	Publication	Country or				lation
Imitial/)	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	BUU	0 200 383	04/07/1986	Europe				
	BVV	0 225 189	11/28/1986	Europe				
	BWW	0 272 0978	06/22/1988	Europe				
	BXX	0 312 052 A1	10/1987	Europe			-	
	BYY	0 360 340	03/28/1990	Europe				
	BZZ	0 364 235 A1	04/1988	Europe				
	CA	0 383 751	09/1994	Europe				
	СВ	0 455 463	11/06/1991	Europe				
	CC	1,242,211	08/11/1971	United Kingdom				
	CD	1,520,247	08/02/1978	United Kingdom				
	CE	1,527,605	10/04/1976	United Kingdom				
	CF	1,569,611	06/18/1980	United Kingdom				
	CG	2,115,065	06/11/1993	Canada				
	СН	43556/93	01/04/1994	Australia				
	CI	8 007 820-7	11/17/1986	Sweden				
	CJ	9 302 198-8	06/1993	Sweden				
	CK	9 400 371-2	02/1994	Sweden				
A V V	CL	DD 261 096 A1	10/19/1988	Germany				
an all	СМ	GB 837,465	06/15/1960	Great Britain				
IL	CN	Hei 4-149126	05/22/1992	Japan				
YK	СО	Hei 4-41421	02/12/1992	Japan				
\succ	СР	JP1117825	02/10/1987	Japan				
X	CQ	JP4041421	06/1990	Japan				
X	CR	JP4149126	1992	Japan				
#Ln	CS	JP632932	07/01/1988	Japan				
Dock	CT	WO 87/05213 A1	09/1987	WIPO				
YZ.	CU	WO 88/09163	12/01/1998	PCT				

	<u></u>		1		1 1	1	
Examiner Signature /	~ /			\mathcal{T}	77	;	Date Considered 6
	/ /	M	/ /·	- 1	,		2 1 4
l &	Ŋ	WIN	'	, //	M	AA S	I - I - D
EVALUED LUCE		<u> </u>	\sim				2100
EXAMINER: Initials cita	tion co	nsidered	f. Draw	line	throug	gh citation	if not in conformance and not considered. Include copy of this form with
next communication to a	ipplica	nt.				_	

	Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office			
	i e	closure Statement pplicant			
(Use several sheets if necessary)		heets if necessary)	Filing Date	Group Art Unit	
	(37 CFR §1.98(b))				

	Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Trans Yes	lation No	
	CV	WO 90/04962	05/17/1990	PCT					
	CW	WO 90/07333	04/12/1990	PCT					
	СХ	WO 91/16038	10/31/1991	PCT					
	CY	WO 91/16882	11/14/1991	PCT					
	CZ	WO 91/16929	11/14/1991	PCT					
	CAA	WO 91/18091 A1	11/19/1991	PCT					
	CBB	WO 92/04069	03/19/1992	PCT					
00	ccc	WO 92/06704	04/30/1992	PCT					
X	CDD	WO 92/08446	05/29/1992	PCT					
	CEE	WO 93/25198	12/23/1993	PCT					
	CFF	WO 94/07514	04/14/1994	PCT					
	CGG	WO 94/22461	10/13/1994	PCT					
	СНН	WO 95/00128	01/1995	PCT					
	CII	WO 95/00151	01/05/1995	PCT					
	CJJ	WO 96/19206	06/1996	PCT					
	CKK	WO 96/19207	06/1996	PCT					
XX	CLL	WO 97/10850	03/27/1997	PCT					

	Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner					
Initial	Desig. ID	Document			
\times		"Diabetes Mellitus" Ch. XI in Scientific American Medicine, Scientific American, Inc. (1993)			
X_0		Allenby et al. "The Absorption of Insulin Across the Respiratory Tract of the Guinea-Pig (U)" The Aersol Society, Fourth Annual Conference 129-134 (1990)			
	coo	Almer et al. Diabetes Research and Clin. Pract. 5:s163 (1988)			
DL	СРР	Aungst et al, "Comparison of Nasal," The Journal of Pharmacology and Experimental Therapeutics 244:23-27 (1987)			
\rightarrow		Aungst et al. "Comparison of the Effects of Various Transmucosal Absorption Promoters on Buccal Insulin Delivery" Int. J. Pharm. 53(3):227-235 (1989)			
	CRR	Barbaud Clinical Reviews in Allergy and Immunology 13(3):253-263 (1995)			

	010		
Examiner Signature	a Rhan	Date Considered	2-1-06
EXAMINER: Initials citation considered. Draw linext communication to applicant.	ne through citation if not in	n conformance and no	ot considered. Include copy of this form with
			Substitute Disdosure Form (PTO-1449)

10/792201

	10/	792 201	Sheet <u>7</u> of <u>10</u>
Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-004003	Application No.
by A	closure Statement pplicant	Applicant Bäckström et al.	
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date	Group Art Unit

	Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner Initial	Desig. ID	Document			
X	C98-	Björk et al. "Degradable Starch Wicrospheres as a Nasal Delivery System for Insulin" Int. J. Pharm. 47.233-238 (1988)			
DL	CTT	Bjork et al., "Characterization of degradable starch" Int. J. Pharmaceutics 62:187-192 (1990)			
X	CUO	Björk "Comprehensive Summaries of Uppsala Dissertations from the Faculty of Pharmacy" Acta Univ. Uppsala 103 (1993)			
	CVV	Björk "Starch Microspheres as a Nasal Delivery System for Drugs" Comprehensive Summaries of Uppsala Dissertations from the Faculty of Pharmacy 103 (1993)			
X	EWW	Brange et al "Monomeric Insulins and their Experimental and Clinical Implications" Diabetes Care 13:923-954 (1990)			
A # 2	CXX	Byron et al., "Drug Delivery via the Respiratory" Journal of Aerosol Medicine 7:49-75 (1994)			
SK	CYY	Chandler et al. "Nasal Absorption Rats. II. Effect of Enhancers on Insulin Absorption and Nasal Histology" Int. J. Pharmaceutics 76:61-70 (1991)			
X	CZZ	Chien et al. "Intranasal Drug Delivery for Systemic Medications" CRC Critical Reviews in Therapeutic Drug Carrier Systems 4:67-194 (1987)			
L.	DA	Chien et al, "Potential Developments in" Drug Development and Industrial Pharmacy 15(10):1601-1634 (1989)			
	DB	Colthorpe et al, "The Pharmacokinetics" Pharmaceutical Research 9(6):764-768 (1992)			
	DC	Cutie et al. "The Role of the Dispersing Agents in Inhalation and Intranasal Aerosol Suspensions" Aerosol. Age 30:52-54 (1985)			
	DD	Dahlbäck et al. "Regional Administration of Drugs to the Rabbit Respiratory Tract, Effects on Absorption" J. Aerosol. Medicine 1:222-223 (1988)			
	DE	Damsay et al. Diabetes Res. and Clin. Pract. 5:s163 (1988)			
	DF	Dempster et al. "Anabolic Actions of Parathyroid Hormone on Bone" Endocrine Reviews 14: 690-709 (1993).			
	DG	Edman et al. "Routes of Delivery: Case Studies" Advanced Drug Delivery Reviews 8:165-177 (1992)			
V	DH	Elliott et al. "Parenteral absorption of insulin" Aust. Paediatr. J. 23:293-297 (1987)			
DK_	DI	Eppstein et al. "Alternative Delivery Systems for Peptides and Proteins as Drugs" CRC Critical Reviews in Therapeutic Drug Carrier Systems 5:99-139 (1988)			
\searrow	101	Gonf et al., "Palmitoylcarnitime, a surface active metabolite" FEBS Lett. 390:1-5 (1996)			
	DK	Gordon et al. "Nasal Absorption of Insulin: Enhancement by Hydrophobic Bile Salts" <i>Proc. Natl. Acad. Sci. USA</i> 82:7419-7423 (1985)			
DI	DL	Hirai et al. "Effect of Surfactants on the Nasal Absorption of Insulin in Rats" Int. J. Pharmaceutics 9:165-172 (1981)			
_ & &	DM	Hoover et al, "Peptides are Better," Pharmaceutical Research 9(8):1103-1106 (1992)			
X	E	Igawa et al. "Effect of Absorption Promoters in Intranasal Administration of Human Fibroblast Interferon as a Powder Dosage Form in Rabbits" Chem. Pharm. Bull. 37:418-421 (1989)			
W.C.	DO	Jacobs et al. "The Pharmacodynamics and" Diabetes 42:1649-1655 (1993)			
	\sim	A 0			

Examiner Signature / / /	////	Date Considered O
V 6. \d/	Plaka	9 / > ^ /
	Lu Man	J = J = IJb
CYALANIES LINE III	700/000	2
EXAMINER: Initials citation considered.	Draw line through citation if no	t in conformance and not considered. Include copy of this form with
next communication to applicant.		The second secon

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office			
1	closure Statement pplicant	Applicant Bäckström et al.		
(Use several sheets if necessary)		Filing Date	Group Art Unit	
(37 CFR §1.98(b))			1	

Desig. ID Design. Id Desig. Id		Other Documents (include Author, Title, Date, and Place of Publication)				
DP Jaegfeld et al. "Particle size distribution from different modifications of Turbuhaler" Proceedings of an international workshop on a new inhaler 21-22-90-99 (1987) Jones "Pulmonary Absorption of Insulin" Ph.D. Thesis, Welsh School of Pharmacy, University of Wales, United Kingdom (1998) DR Kalinkova International Journal of Pharmaceutics 187(1):1-15 (1999) DS Köhler et al. "Pulmonary Administration" Diobetes 33:75A (1984) DT Köhler et al. "Non radioactive procedure for the measurement of lung permeability: inhalation of insulin" *AtemwLungenkrkh., Jahrgang 13:230-232 (1987) DU Köhler "Acrosols for Systemic Treatment" *Lung Supp 1:677-684 (1990) Komada et al. "Intratracheal Delivery of Peptide and Protein Agents: Absorption from Solution and Dry Powder by Rat Lung" *J. Pharm. Sci. 83:863-867 (1994) DW Lasker "The Diabetes Control and Complications Tajal" *N.Engl. J. Med. 329:1035-1036 (1993) Lasker "The Diabetes Control and Complications Tajal" *N.Engl. J. Med. 329:1035-1036 (1993) Lace tet al. "Reskfiniary Shady of the Efficacy of Inkulin Aerosol Delivered by Oral Inhalation in Polabetic Patients" *J.M.M. 269:2106-2109 (1993) DY Lecluyse et al. "In Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transcriptical Electrical Resistance and Morphology of Rat Colonic Mucosa" *J. Pharmacol. Exp. Ther. 265(2):955-956 (1993) DZ Lee et al. "Development of an Aerosol Dosage Form Containing Insulin" *J. Pharmaceutical Sciences 65(4):567-574 (1976) DBA Desertal American Chemitical Society 301-309 (1987) DBB Lee et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enhancers for Facilitation of Peptide and Protein Drug Absorption" *Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DCC Lee et al. "Wulmonary Delivery of Free" *Pharmaceutical Research 10:228-232 (1993) DEE Liu et al. "Pulmonary Delivery of Free" *Pharmaceutical Research 10:228-232 (1993) DFF Jones and *Pharmaceutical Research 10:228-232 (1993) DFF Jones and *Pharmaceut	1	Dosia ID	Dogument			
DQ Jones "Pulmonary Absorption of Insulin" Ph.D. Thesis, Welsh School of Pharmacy, University of Wales, United Kingdom (1998) DR Kalinkova International Journal of Pharmaceutics 187(1):1-15 (1999) DS Köhler et al. "Pulmonary Administration" Diabetes 33-75A (1984) DT Köhler et al. "Non radioactive procedure for the measurement of lung permeability: inhalation of insulin" AtternwLungenkrkh., Jahrgang 13:230-232 (1987) DU Köhler "Aerosols for Systemic Treatment" Lung Supp 1:677-684 (1990) DV Köhler "Aerosols for Systemic Treatment" Lung Supp 1:677-684 (1990) DV Köhner "Aerosols for Systemic Treatment" Lung Supp 1:677-684 (1990) DV Köhner "Aerosols for Systemic Treatment" Lung Supp 1:677-684 (1990) DV Lafsker "The Diabetes Control and Complications Trial" N. Engl. J. Med. 329:1035-1036 (1993) Lafsker "The Diabetes Control and Complications Trial" N. Engl. J. Med. 329:1035-1036 (1993) Laby Et al. "Rightminary Shedy of the Efficacy of Insulin Aerosol Delivered by Oral Inhalation in Protein Patients" J. M.M. 269:2106-2109 (1993) Lectuyse et al. "In Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" J. Pharmacol. Exp. Ther. 265(2):955-962 (1993) DZ Sciences 65(4):567-574 (1976) DAA Dee-et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enhancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991) DCC Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Sci. 80:725-729 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Songton of Insulin in Ratis" J. Pharm. 10:624-631 (1987) DFF Mispirme et al. "States on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rasis" J. Pharm. 20:624-631 (1987) DFF Mispirme et al. "Effects of Various Abs			Jaegfeldt et al. "Particle size distribution from different modifications of Turbuhaler"			
DS Köhler et al. "Pulmonary Administration" Diabetes 33:75A (1984)	O Sh	DQ	Jones "Pulmonary Absorption of Insulin" Ph.D. Thesis, Welsh School of Pharmacy, University of			
Köhler et al. "Non radioactive procedure for the measurement of lung permeability: inhalation of insulin" *AtemwLungenkrkh., Jahrgang 13:230-232 (1987) DU Köhler "Aerosols for Systemic Treatment" *Lung Supp 1:677-684 (1990) Komada et al. "Intratracheal Delivery of Peptide and Protein Agents: Absorption from Solution and Dry Powder by Rat Lung" *J. Pharm. Sci. 83:863-867 (1994) **DW*** Lasker "The Diabetes Control and Complications Taial" *N.Engl. J. Med. 329:1035-1036 (1993) Lasker "The Diabetes Control and Complications Taial" *N.Engl. J. Med. 329:1035-1036 (1993) Lestury et al. "In Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" *J. Pharmacol. Exp. Ther. 265(2):955-962 (1993) DZ Lee et al. "The Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" *J. Pharmacol. Exp. Ther. 265(2):955-962 (1993) DE Lee et al. "The Powled promet of an Aerosol Dosage Form Containing Insulin" *J. Pharmaceutical Sciences 65(4):567-574 (1976) DAA Desertal. *American Chemical-Society 301-309 (1987) DE Lee et al. "Intransals Bioavailability of Insulin Powder Formulations: Effect of Permeation Ennancer-to-Protein Ratio" *J. Pharm. Sci. 80:725-729 (1991) DC Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" *Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" *Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" *Pharmaceutical Research 10:228-232 (1993) DFF Shepp" *J. Pharm. Sci. 76(5):351-355 (1987) Misbirne et al. "Effects of Sodium Taurodhydrofusidate on Nasal Absorption of Insulin in Rats" *J. Pharma. 10:624-631 (1987) Misbirne et al. "Renal Handling of Phosphate" *Physiological Reviews 65(2):431-466 (1985) Morate et al. "Renal Handling of Phosphate" *Physiological Reviews 65(2):431-466 (1985) Morate et al. "Ren	XX	DR	Kalinkova International Journal of Pharmaceutics 187(1):1-15 (1999)			
insulin" AtemwLungenkrkh., Jahrgang 13:230-232 (1987) DU Köhler "Aerosols for Systemic Treatment" Lung Supp 1:677-684 (1990) DV Komada et al. "Intratracheal Delivery of Peptide and Protein Agents: Absorption from Solution and Dry Powder by Rat Lung" J. Pharm. Sci. 83:863-867 (1994) DW Lasker "The Diabetes Control and Complications Tipal" N. Engl. J. Med. 329:1035-1036 (1993) Laube et al. "Reinfiniary Study of the Effecty of Insulin Aerosol Delivered by Oral Inhalation in Diabetic Patients" JAMA 269:2106-2109 (1993) Lecluyse et al. "In Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" J. Pharmacol. Exp. Ther. 265(2):955-962 (1993) DZ Lee et al. "Development of an Aerosol Dosage Form Containing Insulin" J. Pharmaceutical Sciences 65(4):567-574 (1976) DAA Desertal American Chemical Society 301-309 (1987) Lee et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enahancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991) DCC Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Mishing et an Sci. 76(5):351-355 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Moria et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Moteculal Weighth" Bott. Pharm. Bull. 16:269-262 (1993) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	X) S	Köhler et al. "Pulmonary Administration" Diabetes 33:75A (1984)			
DV Komada et al. "Intratracheal Delivery of Peptide and Protein Agents: Absorption from Solution and Dry Powder by Rat Lung" J. Pharm. Sci. 83:863-867 (1994)		DT				
and Dry Powder by Rat Lung" J. Pharm. Sci. 83:863-867 (1994) DW Lasker "The Diabetes Control and Complications Taial" N. Engl. J. Med. 329:1035-1036 (1993) Labe et al. "Reikfininary Study of the Efficacy of Inhulin Aerosol Delivered by Oral Inhalation in Diabetic Patients" J. J. MAA 269:2106-2109 (1993) Lecluyse et al. "In Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" J. Pharmacol. Exp. Ther. 265(2):955-962 (1993) Lee et al. "Development of an Aerosol Dosage Form Containing Insulin" J. Pharmaceutical Sciences 65(4):567-574 (1976) DAA Desertal. American Chemical Society 301-309 (1987) Lee et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enahancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991) DCC Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Longnecker et al. "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep" J. Pharm. Sci. 76(5):351-355 (1987) DOGS Mishima et al. "Swdies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Ratis" J. Pharma. 10:624-631 (1987) DIH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) DIH Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Rowder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	Set	DU	Köhler "Aerosols for Systemic Treatment" Lung Supp 1:677-684 (1990)			
Laube et al. "Relifininary Study of the Efficacy of Intulin Aerosol Delivered by Oral Inhalation in Diabetic Patients" JAMA 269:2106-2109 (1993) Lecluyse et al. "In Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" J. Pharmacol. Exp. Ther. 265(2):955-962 (1993) DZ Lee et al. "Development of an Aerosol Dosage Form Containing Insulin" J. Pharmaceutical Sciences 65(4):567-574 (1976) DAA Dee et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enahancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991) DCC Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) DIJ Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	Sh	DV				
in Diabetic Patients" JAMA 269:2106-2109 (1993) Lecluyse et al. "In Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" J. Pharmacol. Exp. Ther. 265(2):955-962 (1993) DZ Lee et al. "Development of an Aerosol Dosage Form Containing Insulin" J. Pharmaceutical Sciences 65(4):567-574 (1976) DAA Dee et al. American Chemical Society 301-309 (1987) Lee et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enahancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991) DCC Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Dods Mishima et al. "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Mishima et al. "Stadies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Moria et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Moreculal Weights" Brol. Pharm. Bull. 16:269-262 (1993) Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	X	DW				
DY Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" J. Pharmacol. Exp. Ther. 265(2):955-962 (1993) DZ Lee et al. "Development of an Aerosol Dosage Form Containing Insulin" J. Pharmaceutical Sciences 65(4):567-574 (1976) DAA Dee et al. American Chemical Society 301-309 (1987) DBB Lee et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enhancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991) DCC Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Longnecker et al. "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Misbirna et al. "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Moria et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Moleculal Weight." Biol. Pharm. Bull. 16:269-262 (1993) DJJ Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	X	- DX -	in Diabetic Patients" JAMA 269:2106-2109 (1993)			
DAA Dee et al. American Chemical Society 301-309 (1987) Lee et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enahancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991) DCC Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Longnecker et al. "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Miskima et al. "Stradies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Moleculal Weights" Biol. Pharm. Bull. 16:269-262 (1993) DJJ Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	M	DY	Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" J. Pharmacol.			
DBB Lee et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enahancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991) DCC Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Longnecker et al. "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Mishima et al. "Stadies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Moleculal Weights" Biol. Pharm. Bull. 16:269-262 (1993) DJJ Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	De	DZ				
Enahancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991) Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Longnecker et al. "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Mishima et al. "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Moleculal Weights" Biol. Pharm. Bull. 16:269-262 (1993) Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	×.	DAA	Lee et al. American Chemical Society 301-309 (1987)			
Absorption" Critical Rev. Therapeut. Drug Carrier Systems 8:191-192 (1991) DDD Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993) DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) DFF Longnecker et al. "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Mishima et al. "Stadies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Molecular Weights" Biol. Physiol. Bull. 16:269-262 (1993) DJJ Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)		DBB	Enahancer-to-Protein Ratio" J. Pharm. Sci. 80:725-729 (1991)			
DEE Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993) Longnecker et al. "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Misbirna et al. "Sudies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Molecular Weights" Biol. Pharm. Bull. 16:269-262 (1993) DJJ Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	D.	DCC				
DFF Longnecker et al. "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Mishima et al. "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Molecular Weights" Biol. Pharm. Bull. 16:269-262 (1993) DJJ Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)		DDD	Li et al. "Effect of a" Eur. J. Pharm. Biopharm. 39:216-221 (1993)			
Sheep" J. Pharm. Sci. 76(5):351-355 (1987) Mishima et al: "Straties on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Molecular Weights" Biol. Pharm. Bull. 16:269-262 (1993) Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	Los	DEE	Liu et al. "Pulmonary Delivery of Free" Pharmaceutical Research 10:228-232 (1993)			
Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987) DHH Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985) Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Molecular Weights" Biol. Pharm. Bull. 16:269-262 (1993) DJJ Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	<i>DL</i>	DFF	Sheep" J. Pharm. Sci. 76(5):351-355 (1987)			
Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Molecular Weights" Biol. Pharm. Bull. 16:269-262 (1993) DJJ Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	X	D06	Mishima et al. "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" J. Pharma. 10:624-631 (1987)			
Different Moleculal Weights" Biol. Pharm. Bull. 16:269-262 (1993) Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	L DK	DHH	Mizgala et al. "Renal Handling of Phosphate" Physiological Reviews 65(2):431-466 (1985)			
32:1040-1047 (1983) Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" J. Controlled Release 1:15-22 (1984)	X	DIE	Different Molecular Weights" Biol. Pharm. Bull. 16:269-262 (1993)			
1:15-22 (1984)	De	DJJ	32:1040-1047 (1983)			
DLL Nagano et al. "New Method of Insulin" Jikeikai Med. J. 32:503-506 (1985)	X	-BAKK/				
	L DL	DLL	Nagano et al. "New Method of Insulin" Jikeikai Med. J. 32:503-506 (1985)			

			·
	\wedge		/
Examiner Signature	,) 11 1/1 1	Date Considered	
	Lew Kuloson		^ /
\ \hlimit{\lambda}	CIXUIX KA/WXQXX	1 2111	D W
	2000		<u> </u>
EXAMINER: Initials citation of	considered. Draw line through citation if n	ot in conformance and not considered. Incl	ude copy of this form with
next communication to applica	ant.		

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-004003	Application No.
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Bäckström et al.	
		Filing Date	Group Art Unit
(37 CFR §1.98(b))			ŀ

	Other Documents (include Author, Title, Date, and Place of Publication)			
Examine Initial	r Desig. ID	Document		
DMM		Newman, "Chapter 9: Therapeutic aerosols" Aerosols and the Lung: Clinical and Experimental Aspects, Butterworth & Co., United Kingdom (1984)		
	DNN	O'Hagan et al. "Absorption of Peptides and Proteins from the Respiratory Tract and the Potential for Development of Locally Administered Vaccine" CRC Critical Reviews in Therapeutic Drug Carrier Systems 7:35-97 (1990)		
	DOO	Okumura et al. "Intratracheal delivery of insulin absorption from solution and aerosol by rat lung" International Journal of Pharmaceutics 88:63-73 (1992)		
	DPP	Olanoff et al. "Method to Enhance Intranasal Peptide Delivery" Controlled-Release Technology Pharmaceutical Applications		
	DQQ	Patton et al. "(D) Routes of Delivery: Case Studies" Advanced Drug Delivery Reviews 8:179-196 (1992)		
IK N	O DRR	Patton et al. "Bioavailability of Pulmonary Delivered Peptides and Proteins: α-interferon, Calcitonins and Parathyroid Hormones" Journal of Controlled Release 28:79-85 (1994)		
		Pifferi FARMACO 54(1-2):1-14 (1999)		
X		Pontiroli et al. "Nasal Administration of Glucagon and Human Calcitonin to Healthy Subjects: a Comparison of Powders and Spray Solutions and of Different Enhancing Agents" Eur. J. Clin. Pharmacol. 37:427-430 (1989)		
DUU		Remington's Pharmaceutical Science, 18th Edition, p. 1079 (1990)		
1	DVV	Ruin "Diabetics May Not Need Their Insulin Shots" Sydsvenska (Dagbladet) (1989)		
	DWW Sakr "A new approach for insulin" International Journal of Pharmaceutics 86:1-7 (1992)			
	DXX Salzman et al., "Intranasal Aerosolized Insulin Mixed-Meal Studies and Long-term Use in Type Diabetes" The New England Journal of Medicine 312:1078-1084 (1985)			
X	Schipper et al. "Nasal Insulin Delivery with Dimethyl-β-Cyclodextrin as an Absorption Enhancer in Rabbits: Powder More Effective than Liquid Formulations" <i>Pharmaceutical Research</i> 10:682-686 (1993)			
DL	DZZ Schluter et al. "Pulmonary Administration Type 1 Diabetics" Abstract #298, Diabetes, 33 (Supplement): 75A (1984)			
$\square \times$	Selameral. "Devices for Insulin Administration" Diabetes Care 13:955-979 (1990)			
X	AB	The Diabetes Control and Complications Trial Research Group "The Effect of Intensive Treatment of Diabetes on the DevelopmentComplications in Insulin-Dependent Diabetes" N. Engl. J. Med. 329:977-986 (1993)		
	EC Timsina et al. "Drug Delivery to the Respiratory Tract Using Dry Powder Inahlers" Int. J. Pharmaceutics 101:1-13 (1994)			
X	5401	Toutou et al "Targeted Enteral Delivery of Inculin to Pats" Int. I. Pharm. 30(2-3):05-100		
Z	the last	· · · · · · · · · · · · · · · · · · ·		
The state of the s	EF	EF Wearly "Recent Progress in Protein and Peptide Delivery by Noninvasive Routes" Critical Rev. Therapeut. Drug Carrier Systems 8:331-394 (1991)		
A	EG	Wetterlin "Turbuhaler: A New Powder Inhaler for Administration of Drugs to the Airways" Pharmaceutical Research 5:506-508 (1988).		
Examiner Signature Date Considered				

2500 LX Lyngan	2 - 1 - 0 p
EXAMINER: Initials citation considered. Draw line through citation if no	t in conformance and not considered. Include copy of this form with
next communication to applicant.	• • • • • • • • • • • • • • • • • • • •
	Substitute Disclosure Form (PTO-144)

	Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-004003	Application No.
Information Disclosure Statement by Applicant		Applicant Bäckström et al.		
(Use several sheets if necessary)	Filing Date	Group Art Unit		
	(37 CFR §1.98(b))			

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner		
Mitial_	Desig. ID	Document
Sky	EH	Wigley et al. "Insulin Across Respiratory Mucosae by Aerosol Delivery" Diabetes 20:552-556 (1971)
	EI	Yamamoto et al. "Absorption Enhancement of Intrapulmonary Administered Insulin by Various Absorption" J. Pharm. Pharmacol 46:14-18 (1994)
L	EJ	Yoshida et al. "Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form" J. Pharma. Sci. 68:670-671 (1979)
X	EK	Zingg et al. "Transphatic Absorption and Biliary Excretion of Insulin" Can. J. Physiol. Pharmacol. 65:1982-1987 (1987)
X	EL_	Zinman Medical Intelligence The Physiologic Replacement of Insulin" N. Engl. J. Med. 321:363-320 (1989)

Savil Lyklon

2-1-06

Examiner Signature

Date Considered